

K091954

510(k) SUMMARY

A. Submitter Information:

Submitter: MEDCOMP®
1499 Delp Drive
Harleysville, PA-19438
(215) 256-4201 Telephone
(215) 256-9191 Fax
Contact: Susan Pileggi
Date Prepared: June 26, 2009

JAN - 8 2010

B. Device Name: Micro-Stick® Set

Common Name: Introducer Set
Classification Name: Catheter Introducer (74 DYB)
C.F.R. Section: 880.1340
Class: II

C. Predicate Devices:

K071574: Enpath Medical Inc, Stiffer Coaxial Micro-Introducer Set
K990705: MedAmicus Inc, MedAmicus Coaxial Introducer

D. Device Description:

The Micro-Stick® Set is designed to provide dilation of the initial entry point and provide a channel for attaining vascular access. The coaxial introducer consists of an inner dilator within a slightly shorter outer sheath.

The kit contains a 21 gauge introducer needle, a .018" diameter guidewire, and a 4F or 5F coaxial introducer. The coaxial introducer is offered in a standard and stiff version.

The Micro-Stick® Set is packaged sterile.

E. Intended Use:

The Micro-Stick® Set is indicated for percutaneous introduction of up to a 0.038 inch guidewire or catheter into the vascular system following a small 21 gauge needle stick. The Micro-Stick® Set is not intended for use in the coronary or cerebral vasculature.

F. Comparison to Predicate Devices:

The Micro-Stick® Set is substantially equivalent to the predicate devices in terms of intended use, anatomical location, general design, and method of sterilization.

G. Bench / Performance Data:

The following in-vitro testing was performed on the Micro-Stick® Set to assure reliable design and performance in accordance with ISO standards and/or internal procedures.

- Guidewire Passage
- Air Leakage
- Liquid Leakage
- Force at Break
- Simulated Use

H. Biocompatibility:

Results for all biocompatibility testing demonstrate the materials used meet the requirements of ISO 10993.

I. Conclusion:

The proposed devices meet the performance criteria of design verification as specified by ISO standards and test protocols. The proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed devices are substantially equivalent to the legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

MedComp
c/o Ms. Susan Pileggi
1499 Delp Drive
Harleysville, PA 19438

JAN - 8 2010

Re: K091954
Micro-Stick Set
Regulation Number: 21 CFR 880.1340
Regulation Name: Introducer Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: November 24, 2009
Received: November 24, 2009

Dear Ms. Pileggi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

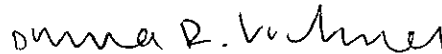
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. .

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K091954

Device Name: Micro-Stick® Set

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-
CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana E. Velazquez
(Division Sign-Off)
Division of Cardiovascular Devices

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